DENTAL COMPOSITION FOR THE MINERAL OCCLUSION OF DENTINAL TUBULES IN SENSITIVE TEETH

[0001] This patent application claims the filing date of provisional patent application Serial No. 60/147,438 filed on Aug. 5, 1999.

FIELD OF THE INVENTION

[0002] The present invention relates generally to compositions and methods for their use in the alleviation of dental pain associated with sensitive teeth.

BACKGROUND OF THE INVENTION

[0003] Dentin is a hard but resilient calcareous tissue that mechanically supports the dental enamel. The dentin encloses and protects the pulp. The human tooth is comprised of a layer of enamel which is composed mainly of rods or prisms that are held together by an interprismatic cementing substance. The enamel covers the dentin which surrounds the pulp cavity and root canal. The root surface is covered by cementum The pulp cavity and root canal are filled with connective tissue which contains fibroblasts, histocytes, odontoblasts, blood vessels and nerves. The dentin also has a large number of continuous dentinal tubules which connect the pulp cavity with the dentinoenamel/cementum junction. These fine dentinal tubules radiate out from the pulp. In a sound tooth, the distal end of each tubule is generally covered by enamel or cementum, or by posteruptive deposits such as salivary mineral, or by a transient smear layer from mechanical burnishing. Posteruptive deposits may appear and disappear over the course of time as a consequence of various processes such as mineralization, demineralization, erosion, burnishing and abrasion.

[0004] The problem of tooth sensitivity arises when the enamel and cementum are worn away from the tooth by either improper oral hygiene practices or as a result of periodontal disease and/or its treatment. The dentinal tubules are fluid-filled exposing the central core of the tooth to the external environment. Hence, when subjected to air current, tactile or thermal stimulation, the pulpal nerves are irritated, leading to the perception of pain. It is well established in the scientific literature that the aforementioned stimuli evoke pain by inducing fluid movement within the dentinal tubules. In recent years, due to increased human longevity, an increasing number of people suffer from gingival degeneration and periodontitis. This trend magnifies the clinical significance of sensitive dentin.

[0005] The hydrodynamic theory is currently the predominant explanation of sensitive dentin. According to this theory, the stimuli conveyed through dentinal tubules irritates nerves distributed in the dental pulp causing pain in these areas. Suppressing sensitive dentin and ameliorating or alleviating the pain might be achieved by sealing the dentinal tubules, thus blocking the conductor of the sensation by physical or chemical means.

[0006] It is the fluid movement which in turn leads to activation of sensory nerve endings near the dentin/pulp boarder. The therapeutic approaches to treating dentin sensitivity involve either the reduction in the excitability of the intradental nerves by agents such as potassium ions or the reduction in the hydraulic conductance of the dentinal tubules by agents such as oxalate compounds as disclosed in U.S. Pat. No. 4,057,621. U.S. Pat. No. 5,037,639 discloses a method for the treatment of the pain associated with sensitive teeth through the application of compositions comprising calcium phosphate compounds that are formed via precipitation in situ. U.S. Pat. No. 5,027,031 discloses a dentifrice wherein the composition is rich in the salts of high molecular weight polyelectrolyte compounds. U.S. Pat. No. 5,250,288 teaches applying an effective amount of a charged polymeric particle to the surface of the tooth so that the particles enter and occlude the dentinal tubules. U.S. Pat. No. 5,244,651 discloses a composition with a colloid produced by mixing the salt of a polyvalent metal and a polyphosphate and/or a water-soluble salt thereof.

[0007] U.S. Pat. No. 5,330,746 discloses a dental varnish used to prevent bacterial plaque formation, periodontal disease and tooth sensitivity comprising an acrylic polymer, a hydrophilic polymer or a combination of the two with a strontium salt incorporated therein for long term sustained release. Other possible compounds for alleviating the pain associated with sensitive teeth include potassium, sodium and lithium nitrate (U.S. Pat. No. 3,863,006), potassium chloride and potassium bicarbonate (U.S. Pat. Nos. 4,631, 185 and 4,751,072). U.S. Pat. No. 5,133,957 discloses a composition consisting of two co-polymerizable monomers which are polymerized in situ thereby occluding the dentin tubules. U.S. Pat. No. 5,374,417 discloses a potassium salt of a synthetic anionic polymer to close the dentinal tubules thus preventing the subsequent penetration of external stimuli to the dental pulp.

[0008] All of the above referenced materials use biologically inactive organic or inorganic components that will not sufficiently block or occlude the dentinal tubules so as to completely "desensitize" sensitive teeth. Normal habits including the eating of acidic foods and oral hygiene maintenance will remove these materials.

[0009] Applying a different approach to provide for at least partial occlusion of dentinal tubules, U.S. Pat. No. 5,735,942 ("'942 patent") discloses a bioactive melt-derived glass composition for the treatment of tooth hypersensitivity. The '942 patent discloses the following composition by weight percentage: 40-60 SiO_2, 10-30 CaO, 10-35 Na_2O, 2-8 P_2O_5, 0-25 CaF_2 and 0-10 B_2O_3, with particle size of less than about 10 μm with some particles about 2 μm or less and some larger than 2 μm. The '942 patent notes that 60% SiO_2 is the maximum silica limit for bioactive melt-derived glass.

[0010] In a melt-derived process, there are three reactions which lead to the development of a porous hydrated silica-gel layer: ion exchange, silica dissolution, and condensation of silanols to form siloxane-bonded hydrated silica chains or rings. As the SiO_2 content increases in melt-derived glasses, the rates of these reactions decrease, reducing the availability of Ca^{+2} ions in solution and the ability to develop the silica-gel layer on the surface. The result is the reduction and eventual elimination of the bioactivity of the melt-derived glasses as the SiO2 content approaches 60%. The process imposes narrow effective compositional zones which hinder the formulator's ability to modify and tailor the material for a specific application.

[0011] Bioactive glasses prepared by the melt-derived process and as taught in the '942 patent are processed in a